

CLAIMS

1. A method of simultaneously detecting at least one Hepatitis C Virus (HCV) antigen and at least one HCV antibody in a test sample comprising the steps of:

a) contacting said test sample with: 1) at least one HCV viral antigen or portion thereof coated on a solid phase, for a time and under conditions sufficient for the formation of antibody/antigen complexes and 2) at least one antibody to HCV or portion thereof coated on said solid phase, for a time and under conditions sufficient for the formation of antigen/antibody complexes;

b) detecting said antibody/antigen complexes, presence of said complexes indicating presence of HCV antigen in said test sample; and

c) detecting said antigen/antibody complexes, presence of said complexes indicating presence of HCV antibody in said test sample.

2. The method of claim 1 wherein said at least one HCV antigen coated on the solid phase is selected from the group consisting of core antigen, NS3, NS4, NS5, and portions thereof.

3. The method of claim 2 wherein said at least one antibody coated on said solid phase is a monoclonal antibody selected from the group consisting of 13-959-270, 14-1269-281, 14-1287-252, 14-153-234, 14-153-462, 14-1705-225, 14-1708-269, 14-1708-403, 14-178-125, 14-188-104, 14-283-112, 14-635-225, 14-726-217, 14-886-216, 14-947-104, 14-945-218, 107-35-54, 110-81-17, 13-

Sub. B4
Con. id.

09891983-062504

Sub. B.4
contd.

975-157, 14-1350-210, C11-3, C11-7, C11-10, C11-14 and C11-15.

4. The method of claim 3 wherein said at least one antibody coated on the solid phase is not reactive with said at least one antigen coated on the solid phase.

5. The method of claim 1 wherein said at least one antibody is a HCV anti-core monoclonal antibody and said at least one antigen is a recombinant HCV core protein.

6. The method of claim 5 wherein said recombinant core protein does not contain epitopes to which said anti-core monoclonal antibody binds.

7. The method of claim 1 wherein said solid phase is a microparticle.

8. A method for simultaneously detecting the presence of at least one HCV antigen and at least one HCV antibody in a test sample comprising the steps of:

a) contacting said test sample with: 1) at least one HCV viral antigen or portion thereof coated on a solid phase, for a time and under conditions sufficient for the formation of antibody/antigen complexes and 2) at least one HCV antibody or portion thereof coated on said solid phase, for a time and under conditions sufficient for the formation of antigen/antibody complexes;

109290-23676860

Sub. B.5
contd.

Sub. B5

b) adding a conjugate to the resulting antibody/antigen complexes for a time and under conditions sufficient to allow said conjugate to bind to the bound antibody in (a) (1), wherein said conjugate
 5 comprises a second antibody attached to a chemiluminescent compound capable of generating a detectable signal and simultaneously adding a second conjugate to the resulting antigen/antibody complexes for a time and under conditions sufficient to allow
 10 said conjugate to bind to the bound antigen in (a) (2), wherein said conjugate comprises a third antibody attached to said chemiluminescent compound capable of generating a detectable signal; and

c) detecting said generated signal, presence of
 15 said signal indicating presence of at least one antigen in said test sample selected from the group consisting of HCV antigen and HCV antibody.

9. The method of claim 8 wherein said at least one HCV antigen coated on the solid phase is selected from the group consisting of core antigen, NS3, NS4, NS5, and portions thereof.

10. The method of claim 9 wherein said at least
 20 one antibody coated on said solid phase is a monoclonal antibody selected from the group consisting of 13-959-270, 14-1269-281, 14-1287-25, 14-153-234, 14-153-462, 14-1705-225, 14-1708-269, 14-1708-403, 14-178-125, 14-188-104, 14-283-112, 14-635-225, 14-726-217, 14-886-
 25 216, 14-947-104, 14-945-218, 13-975-157 and 14-1350-210, 107-35-54, 110-81-17, C11-3, C11-7, C11-10, C11-14 and C11-15.

FOIA b 7 - E.O. 13526

